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72

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,713	11/27/2000	Genichiro Soma	101149-00008	7273

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,713

Applicant(s)

SOMA ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' amendment, received October 28, 2003 acknowledged. Claims 1-14 and 17 were canceled. Claims 15 and 16 were amended. New claims 18-26 were added.
2. Currently claims 15-16 and 18-26 are pending and under consideration.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

4. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Rejections Moot

5. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,346,891) is moot in view of cancellation of those claims.
6. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Mizuno et al. (WO96/23002) is moot in view of cancellation of those claims.
7. Rejection of claims 1, 2, 6, 9, and 10 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819) is moot in view of cancellation of those claims.
8. Rejection of claim 17 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819) is moot in view of cancellation of the claim.
9. Rejection of claim 6 under 35 U.S.C. 112, first paragraph is moot in view of cancellation of the claim.

Art Unit: 1645

10. Rejection of claims 15-17 under 35 U.S.C. 112, second paragraph is moot in view of cancellation of those claims.

Claim Rejections - 35 USC § 102

11. Claims 15-16 are rejected under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819). Prior art of record.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish. However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. (US Patent No. 5,494,819) teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by

Art Unit: 1645

a strain of the species *Pantoea agglomerans* (see abstract and claim 1).

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Rejections - 35 USC § 103

12. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (US Patent No. 5,641,761) in view of Soma et al. (US Patent No.5, 494,819). Prior art of record.

Claims are drawn to a method of activating immunity or preventing infection in crustaceans or fish comprising administering an effective amount of low molecular weight lipopolysaccharide to crustaceans or fish.

Takahashi et al. teach a method of activating immunity or preventing infection in crustaceans comprising administering or feeding a polysaccharide to crustaceans (see claims). Takahashi et al teach a method of enhancing the immune system of crustaceans (Kuruma prawns, see examples 1-7). Takahashi et al teach a method of treating crustaceans' infections such as vibrio infections, mycotic infections, and viral infections. Takahashi et al. do not teach low molecular weight lipopolysaccharide. However Soma et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low

Art Unit: 1645

molecular weight lipopolysaccharide and capable of activating immunity (see column 5).

The product can be used as feed or feed additives for veterinary use. (see column 5).

It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to modify the method taught by Takahashi et al. by using the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. and with the low molecular weight lipopolysaccharide of Soma et al. which has excellent immuno-stimulating activity and may be provided at low cost and a large amount (see Soma et al., column 2, line 50-55). Limitations such as concentration of the feed are being viewed as limitations of optimizing experimental parameters.

Conclusion

13. No claims are allowed.

14. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1645

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

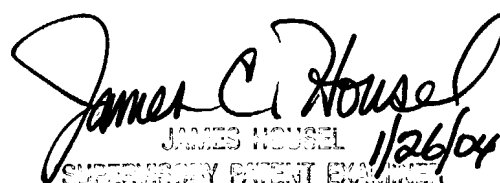
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

01/23/2004


JAMES HOUSEL
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1/26/04